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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,410	04/01/2004	Larry A. Gilbertson	38-15(51091)B	9581
27161 7590 01/18/2007 MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167				
			EXAMINER	
			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/816,410

Applicant(s)

GILBERTSON, LARRY A.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Restriction/Election

Applicant's election without traverse of Group III in the reply filed on 25 October 2006 is acknowledged.

Claims 14-23, corresponding to elected Group III, are examined in the instant Office action. The linking claims are not being examined, since they link Groups I and II, neither of which were elected.

Specification Objection

The specification is objected to on page 1 for its omission of the current status of the parent applications, namely their issuance as US patents. The continuity data on page 1 of the specification should be amended to insert the US patent numbers after the filing dates of each parent application. All specification amendments should comply with 37 CFR 1.121(b).

Claim Objection

Claim 14 and dependents are objected to for their dependency upon non-elected claim 13.

Non-Statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to seed produced from transgenic plants. Due to Mendelian segregation of the transgene following outcrossing, some progeny seed will not contain the transgene, and thus be indistinguishable from naturally-occurring seed.

See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Amending claims 17 and 19 to recite that the seeds comprise the transgene would obviate this rejection. All claim amendments should comply with 37 CFR 1.121(c).

Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Perry (US 6,657,109 filed 02 February 1999).

The claims are drawn to inbred and hybrid maize plants and seed and progeny, which comprise desired transgenes conferring agronomic traits, but which do not comprise reporter or marker genes, or other ancillary DNA sequences. The claims

recite that said plants are produced by cultivating transformed plant callus cells on a medium containing a negative selection agent.

Perry teaches inbred maize plants which comprise a *Bacillus thuringiensis* (B.t.) transgene conferring the agronomic trait of insect resistance, and seeds and progeny thereof (see, e.g., claims 1-2, 8, 11-12, and 18-35). Progeny plants are inherently grown from seed produced by crossing said inbred maize plant with itself or with another maize plant. Perry also teaches a process for producing a derivative of an inbred maize plant which contains a transgene, said process comprising crossing the inbred with another plant containing the transgene (see, e.g., claims 7 and 41-42), wherein said crossing would inherently produce a hybrid maize plant comprising said transgene.

Although Perry does not teach the prior cultivation of the marker gene-free corn callus cells on a medium comprising the selection agent, it appears that the resultant marker gene-free plants taught by Perry are indistinguishable from the claimed marker gene-free plants, despite their alternative process of production.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same

product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Ebinuma et al (US 5,965,791 filed 09 November 1995).

Ebinuma et al teach dicotyledonous plants comprising an agronomic gene of interest but lacking ancillary sequences including marker genes, due to the presence of directly repeated transposon sequences or directly repeated recombination recognition sequences, wherein the removal of marker genes provides environmental and human nutritive benefits (see, e.g., column 1, line 60 through column 2, line 7; claims 1-18; column 11, lines 11-15).

See *Best* and *Thorpe* cited above.

Claims 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dale et al.

Dale et al teach plants and progeny produced by self-pollination (which progeny were inherently grown from seed resulting from said pollination), wherein said plants and progeny lacked ancillary DNA sequences such as selectable marker genes, due to the presence of directly repeated recombinase recognition sequences and the presence of a gene encoding a recombinase, wherein the desired transgene conferring bioluminescence was retained (see, e.g., page 10558, Abstract and paragraph bridging the columns; page 10559; paragraph bridging pages 10560 and 10561).

See *Best* and *Thorpe* cited above.

Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebinuma et al (US 5,965,791 filed 09 November 1995).

The claims are drawn to seed and progeny of plants comprising a desired transgene but free of ancillary DNA sequences including selectable marker genes.

Ebinuma et al teach transformed dicotyledonous plants which do not contain marker genes as discussed above, but do not teach progeny or seeds thereof.

It would have been obvious to one of ordinary skill in the art to utilize the transgenic marker-free plants taught by Ebinuma et al, and to breed and propagate said plants via crossing for the production of seeds and progeny. It is well-known in the art that desired plant genotypes may be propagated by seed and progeny production, and/or that said desirable plant genotypes may be crossed with other desirable plant genotypes, in order to obtain a plant which possesses multiple desirable genes conferring multiple desirable agronomic traits.

Claims 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebinuma et al (US 5,965,791 filed 09 November 1995), in view of Gordon-Kamm et al.

The claims are drawn to monocotyledonous plants transformed with genes conferring agronomic traits, but not containing ancillary DNA sequences like marker

genes, wherein said monocotyledonous plants may include maize, and wherein progeny and seeds thereof are produced.

Ebinuma et al teach dicotyledonous plants transformed with a desired transgene but not comprising a selectable marker gene, as discussed above, but do not explicitly teach transformed monocots including maize or progeny thereof.

Ebinuma et al also suggest the use of a variety of transgenes including the *Bacillus thuringiensis* gene conferring insect resistance, and also suggest the transformation of maize via particle bombardment or a "ballistic" method, to obtain transformed maize plants with desired agronomic genes but free from ancillary marker genes (see, e.g., column 10, lines 42-52; column 11, lines 11-15 and 35-44).

Gordon-Kamm et al teach a ballistic method of transforming maize, and suggest its wide applicability for the introduction of a variety of agronomic genes of interest (see, e.g., page 603, Abstract and paragraph bridging the columns of the Introduction).

Gordon-Kamm et al also teach the importance of obtaining fertile transgenic plants, for the production of seeds and progeny, in order to introduce a variety of new genes in combination into crop plants (see, e.g., pages 609-610).

It would have been obvious to one of ordinary skill in the art to utilize the method of producing marker-free transgenic plants as taught by Ebinuma et al, and to modify that method by incorporating transformed maize plants and their progeny, using the techniques for maize transformation taught by Gordon-Kamm et al, as suggested by each reference. Choice of agronomically desirable and available maize genotype,

whether inbred or hybrid variety, would have been the optimization of process parameters.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 7, 2007

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

1638

